REPORT TO THE TWENTY-THIRD LEGISLATURE STATE OF HAWAII 2006

ON UNUSED PRESCRIPTION DRUGS

PURSUANT TO SECTION 8, ACT 190,
SESSION LAWS OF HAWAII, 2004,
REQUIRING THE DEPARTMENT OF HEALTH
TO REPORT THE IMPLEMENTATION AND OPERATION
OF THE PRESCRIPTION DRUG REPOSITORY PROGRAM
AND DRUG DONATIONS

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STATE OF HAWAII
DEPARTMENT OF HEALTH
DECEMBER 2005

Report to 2006 Legislature Act 190, Section 8, SLH 2004 October 26, 2005 Version

In appropriate circumstances, unused prescription drugs may be a resource to help those in need. Section 8 of Act 190 requires the DOH to report to the legislature difficulties with (1) the implementation and operation of the prescription drug repository program, if any; (2) potential for expansion to include drugs donated by private individuals; (3) possible strategies to provide incentives for dispensing pharmacies or institutional facilities to provide donations of prescription drugs to repositories; and (4) suggested legislation, no later than twenty days before the convening of the 2006 regular session. The DOH has looked at both the donations of pharmaceuticals to drug repositories under HRS chapter 328C and the Return-for-Credit-and-Reuse of Prescription Drugs under HRS chapter 328B.

<u>Difficulties with the implementation and operation of the prescription drug</u> repository program

Implementation and operation of the prescription drug repository program is presently limited to the Medicine Bank in Hawaii, and the Medicine Bank lacks the space and personnel to accept all drug donations which are legally allowed.

The Medicine Bank, the sole drug repository in the state, is currently fulfilling its mission only by using surplus manufacturers' drug samples, packaged by the drug manufacturer in their original, unopened packaging with its labeling intact, and donated by physicians. The Medicine Bank then provides those samples to health clinics statewide and who then dispense them to needy individuals. The law also allows Medicine Bank and any other drug repositories to receive donations, from institutional facilities, previously dispensed, unopened, un-tampered single user units, which are containers provided for the exclusive use by a single patient, such as blister packaged pills prescribed for a single patient.

Long-term care facilities receive the vast majority of patient medications from a pharmacy packaged in blister packs, and these medications, if unused, are not donated for reuse.

Implementation and operation of the program for the return for credit and reuse of prescription drugs have not begun. Section 9 of Act 190, 2004 Session Laws of Hawaii, states that chapter 328B shall not be implemented until administrative rules are adopted that address crediting processes and appropriate handling fees. Credits and handling fees are to be applied to the payer and dispensing pharmacy, respectively, upon the return of a previously dispensed prescription drug from an institutional facility (e.g. long-term care facility) to the dispensing pharmacy. (No rules are required for returns for full credit with no handling fees of prescription drugs refused on delivery, but DOH is unaware of any such cases.) To date the Department of Human Services has not adopted administrative rules under HRS sections 328B-6 and 328B-3(b).

Potential for expansion to include drugs donated by private individuals

Safety and liability are major concerns for any drug donation program and limit the prospects for donations by private individuals under HRS chapters 328B and 328C.

Currently, in HRS 328B, prescription drugs move from the dispensing pharmacy to the institutional facility then back to the dispensing pharmacy. In this situation, due to state and federal regulations of the pharmacies and facilities, there are assurances that the pharmaceuticals are being held and stored properly. Furthermore, pharmacies and facilities use a chain of custody procedure.

Donations by private individuals under HRS chapter 328C are different and more risky. Once the pharmacy relinquishes control of the drug and dispenses it to a private individual, the protective regulations and the chain of custody are lost. There are very little to no assurances the drug would be stored properly (e.g. refrigerated), be free of tampering, and avoid mixtures of expiration dates or dosages, etc. in a single bottle. It is very unlikely a pharmacy or a drug repository would risk reclaiming medication under these circumstances.

<u>Possible strategies to provide incentives for dispensing pharmacies or institutional facilities to provide donations of prescription drugs to repositories</u>

Education of institutional facilities and increasing the drug repository resources may increase donations.

 In an effort to increase awareness of existing drug donation laws (HRS 328C) the Department of Health surveyed 31 long-term care homes, statewide, in December 2004. In addition to educating these institutions about Act 190 (HRS 328B) and HRS 328C, the survey sought information on their donation habits and interest in donating previously dispensed drugs to the Medicine Bank.

Of the 17 surveys returned, only one long-term care home reported actually donating drugs to a repository. However, 13 care homes indicated that they would like to be contacted by the Medicine Bank for more information on donating drugs.

Based on the results from the survey, it appears that some long-term care facilities are interested in taking part in a program that minimizes prescription drug waste; however, currently there appears to be no repository that will take the type of packaged drugs they would predominately be donating. These are drugs bought in bulk from drug manufacturers, which are then repackaged by pharmacists into bottles or blister packs for individual patients.

- 2. In addition, it is unknown how many institutional facilities would take part in the return-for-credit-and-reuse portion of the program, because handling fees charged by these facilities and required processes have yet to be determined. Perhaps once the program is fully implemented, new strategies and incentives may arise to increase donation rate.
- 3. The Medicine Bank is unable to take full advantage of drug donations from institutions like a long-term care facility due to its personnel and space limits. The Medicine Bank is open to exploring ways to handle the donations from long-term care facilities if it obtains more resources.

Suggested legislation

We do not suggest legislation now.

For HRS chapter 328C, more resources for drug repositories might increase the use of donations. Currently the Medicine Bank is the only drug repository in Hawaii. The Medicine Bank needs more resources to better utilize the potential of the drug donation stream. Establishing another drug repository system to augment the Medicine Bank may also increase donations. The DOH is not seeking an appropriation for the Medicine Bank or to establish another drug repository, however.

Without implementing rules for HRS chapter 328B, it is premature to suggest legislation for that program.

Conclusion

There appears to be some potential to expand drug donations under HRS chapter 328C.

Questions clearly remain as to how many institutional facilities and pharmacies will take part in the return-for-credit-and-reuse program under HRS chapter 328B. However, until crediting processes and handling fees are established by rule, HRS 328B cannot be implemented and the program, as designed, cannot be evaluated for effectiveness and possible expansion.

The Department of Health remains committed to encouraging institutional facilities, pharmacies and repositories to work together to achieve the goals set forth in Act 190.